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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDISIM, LTD Plaintiff - Counterdefendant v. BESTMED, LLC Defendant - Counterclaimant	Civil Action No.: 10-cv-2463 (SAS) (RLE)

BESTMED, LLC'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO STRIKE PORTIONS OF PLAINTIFF'S EXPERTS, LIPSON AND KEEGAN

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I. Medisim's Experts Should Be Excluded

Medisim attempts to prop up its baseless lawsuit with the opinions of its purported experts. A cursory review of the expert reports of Lipson and Keegan demonstrate, however, that Medisim's experts' opinions do not satisfy the requirements of Rule 702.

Lipson's expert report is not a product of reliable scientific principles and methods. Lipson fails to adhere to the *Markman* Order, relies on untested and unverifiable procedures, and overlooks well-established law. Keegan's expert report fails to provide a correct time frame, relies on an improper consumer universe, employs inadequate controls, and creates biased results. Thus, Lipson and Keegan should be excluded.

A. Medisim Cannot Hide Lipson's "Deep Tissue Temperature" Re-Construction

Medisim concedes that "deep tissue temperature" is the temperature at a location under the skin. Doc. 64 at 3. Yet, Lipson bases his opinions on a different meaning: a "steady state ... temperature at the measurement site." Doc. 56, Ex. 1 at 11.

The Court warned Medisim that attempts at claim re-construction would result in an exclusion order and possible sanctions. See 10/16/11 Tr. 18-19. Rather than fix the problem, Medisim tries to disguise Lipson's *Markman* do-over with the pretext that he is not re-construing the meaning of deep tissue temperature, but has "made a scientific determination that deep tissue temperature can be calculated" "by allowing the sensors in the [Accused Product] to reach thermoequilibrium at the measurement site." Doc. 64 at 4. Medisim's excuse rings hollow Lipson is opining that "deep tissue temperature" and "steady state temperature" are the same. This obvious claim construction revamp flies in the face of this Court's *Markman* Order.[1]

Lipson's improper departure from the *Markman* Order results in baseless infringement and invalidity opinions. Infringement and invalidity must be based on the claims **as construed**.

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[1] Medisim suggests it did not argue "steady state." Id. at 3-4, n.2. Its "steady state" argument and Lipson's rehash are undeniable. See 4/28/11 Tr. 10:11-11:12 and Doc. 56, Ex. 1 at 11.

Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed.Cir. 2001). Deep tissue temperature does not mean a steady state temperature at the measurement site. Yet, Lipson bases his infringement opinions on Medisim's relinquished "steady state" meaning. His disregard for the stipulated meaning of deep tissue temperature also pervades his opinions on whether pre-critical date sales of the FHT-1 meet this limitation, and his enablement opinions, which hinge on the notion that the prior art teaches prediction of temperatures at a measurement site. Doc. 56, Ex. 3 at 20-26; 17-18. All opinions based on Lipson's concocted equivalent for "deep tissue temperature" are irrelevant, invade the province of the Court, and cause undue confusion.

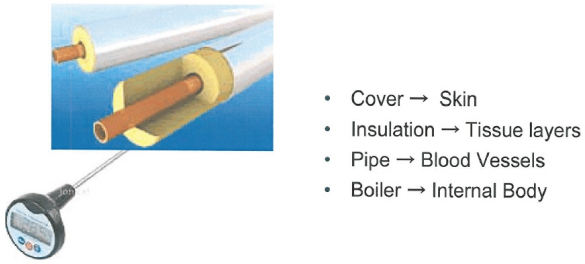
Medisim's excuses for Lipson's flawed water bath tests cannot hide his further disregard for the claims. Doc. 64 at 8. The claims require a processing unit that calculates deep tissue temperature (Doc. 56, Ex. 2, col. 10:10-15), not that measures it directly. Lipson does not measure surface temperature and then calculate water temperature (Lipson's "deep tissue temperature"). Instead, he puts the thermometer in the water to directly measure the actual temperature, just like using a mercury thermometer. Lipson's test is irrelevant.

B. Lipson's "Deep Tissue Temperature" Opinions Fail Under Rule 702

Lipson's deep tissue temperature opinions should also be excluded as being scientifically unreliable. Medisim must prove that Lipson's technique or theory can be or has been tested; has been subject to peer review and publication; or is generally accepted in the relevant community of experts. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593-4 (1993). Such proofs fail on all counts. Medisim incorrectly argues that the dispute about whether Lipson's analysis has scientific basis only raises a factual issue, not a ground for exclusion. Doc. 64 at 5-6. It is well-settled that a lack of scientific basis warrants exclusion. *See Daubert*, 509 U.S. at 591-92.

Lipson cites no testing, scientific basis, peer review, or acceptance of his theory that deep tissue temperature is measurable by "steady state temperature," or ways to test his theory. Doc. 56, Ex. 1 at 11. Medisim proclamation that his theory is a "logical conclusion" based on a

"scientific determination" (Doc. 64 at 4) is meaningless. Theories based solely on an expert's say-so are improper. *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Lipson's premise is also wrong. Skin and tissue are insulators, whose thermal resistance impedes heat transfer between the blood vessel and the skin's surface. Medisim's hot water pipe analogy illustrates this concept.



Doc. 56, Ex. 4. Medisim attempts to dodge its own demonstrative by saying in a footnote it only relates to boiler temperature. Doc. 64 at 7, n.5. It is common sense that a thermometer on the exterior of the insulation will also never reach the temperature of the water in the pipe.

Medisim misrepresents BestMed's expert by claiming he agrees deep tissue temperature is obtained simply with an equilibrium skin surface temperature. Doc. 64 at 6. Goldberg said he assumed *arguendo*, given Medisim's infringement contention, that deep tissue temperature could be measured by determining an equilibrium surface temperature. Ex. A at 17; *see Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889) ("that which infringes if later anticipates if earlier"). Goldberg further discussed Togawa and the understanding in the art that deep tissue temperature may only be determined indirectly from the skin surface in a "zero heat flux" environment. Doc. 61, Ex. A at 58. Lipson did not create this environment.[2] Medisim argues that a thin rubber hood on the Accused Product makes all the difference. Doc. 64 at 5. There is no support for this assertion. Instead, Sessler and Yamakage indicate that a sufficient insulator does not exist.

K-Jump's 510(k) does not prove the legitimacy of Lipson's methods. Medisim argues that

[2] Lipson's own cited reference, Sessler (Ex. B), describes zero heat flux systems as including a thermal flux transducer and a heater to determine temperatures of tissues about a centimeter below the skin surface. Ex. 2. Such a system is also described in Yamakage. Ex. C.

K-Jump's 510(k) theory of estimation shows how deep tissue temperature may be calculated based on a skin's surface temperature. Yet, Lipson relies on this same theory of estimation to posit that the Accused Product calculates "core body temperature," not "deep tissue temperature." Doc. 64 at 7 (“Tc is ‘tissue temperature’”) and Doc. 56, Ex. 1 at 30 (“Tc (core temperature) is being displayed”). These positions are inconsistent, and thus, unreliable.

C. Lipson's "Core Body Temperature" Reconstruction Is Improper

Medisim's argues that "calculating core body temperature" only requires approximating core body temperature, and that a peripheral oral temperature is an approximation. The Court's *Markman* Order makes it very clear peripheral body temperatures, such as an oral temperature, are **not** acceptable as an estimate of core body temperature within the ambit of the '668 Patent. Their thinly-disguised claim construction rehash runs afoul of the entire purpose of the supposed invention, and effectively eviscerates the "core body temperature" limitation.

Lipson argues oral temperature is an accepted estimate of core temperature based on the Erickson article. Doc. 56, Ex. 1 at 7-8. Whether others consider oral temperature to approximate core temperature is inapposite. Infringement must be based on the construed claims, not on third-party articles. The '668 Patent teaches, and this Court correctly held that the claims do not include peripheral temperatures, e.g., oral temperature, in the calculation of a "core body temperature." Doc. 45 at 32-34. Medisim basically argues that the Court's definition of "calculate" opens the door to any measurement that correlates at all to core temperatures, including peripheral temperatures. As the Court held, however, the patent's purpose is to "determine a person's core body temperature in a non-invasive **but more accurate manner**." Doc. 45 at 34, n.127. "It would defy common sense to then define 'core body temperature' to include peripheral temperatures when, according to the '668 Patent itself, there is a 'poor correlation' between peripheral temperatures and core body temperature and peripheral temperatures are not as indicative of the subject's health as temperatures taken at the pulmonary artery." Id.

Basic logic proves Medisim's position to be absurd. The '668 Patent explains there is close correlation between deep tissue and core body temperatures. Doc. 56, Ex. 2, col. 7:6-7. Under Lipson's theory, the patent could have one calculate a deep tissue temperature and then "correct" it to the less accurate peripheral oral temperature. Doc. 56, Ex. 2, col. 10:9-18. Such a nonsensical result defeats the purpose of the supposed invention and highlights Lipson's folly. *See Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14, 26 (Fed.Cir. 2000) (Claims cannot be read in a manner that is contrary to purpose of the invention). The patent makes clear that the calculated core body temperature value must be a more accurate measure of pulmonary artery temperature than deep tissue temperature.

D. Lipson's Methodology Related To Core Body Temperatures Are Unreliable

Lipson failed to test if temperatures displayed by the Accused Products represented the temperature of blood in the pulmonary artery. He misused equipment. He even failed to analyze the source code for the Accused Products. Such facts illustrate the unreliability of his opinions.

Medisim argues, without support, that it need not actually test the Accused Product to see if it displays pulmonary artery blood temperature, but that it is acceptable for Lipson to rely instead on undefined "clinical information in the field." Doc. 64 at 12. The law says otherwise.

Infringement requires a comparison of the claims with the accused device. *Markman v. Westview Instr., Inc.*, 52 F.3d 967, 976 (Fed.Cir. 1995). Temperatures from devices other than the Accused Product are irrelevant to infringement, and will confuse the jury. Lipson could have determined pulmonary artery temperatures with well-known methods. Doc. 56 at 10. Medisim's entreaty that it would be difficult to measure pulmonary artery temperatures is meaningless. Even if it is difficult, it is Medisim's burden to prove that every limitation is met by the Accused Product. *See* e.g., *Zenith Labs. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1424 (Fed.Cir. 1994).

Lipson misused the KD-192, and now gives the excuse that he was merely trying to show that the output of the Accused Product is not actual oral temperature based on his "hot tea" and

"cold water" trials. Doc. 64 at 12. By using the KD-192 thermometer in a manner proscribed by the instructions for use, Lipson necessarily bases his comparison on unreliable readings. Lipson's methods are a clear example of the junk science that *Daubert* directs courts to exclude.

Lipson's lack of reliability is further illustrated by Medisim's incredible claim that analysis of the source code is "irrelevant." Id. at 13. Medisim disingenuously argues that Lipson only failed to analyze the portion of the source code that would confirm whether the Accused Product displayed the actual sensor temperature while in test mode. Id. Not so. Lipson failed to base **any** of his infringement analysis on the executable source code. Doc. 56 at 13. This failure is inexcusable. Medisim must prove the Accused Product calculates deep tissue temperature based on sensor readings, and then corrects this calculated value for a core body temperature. Doc. 56, Ex. 2 at 10:10-18. This two step algorithm, if it existed in the Accused product, would be found in the source code. It is not. Doc. 61, Ex. B at 29-32. Unlike BestMed's expert, Lipson opted not to look.

Lipson hopes to conceal his failure to examine the source code by mixing trials of the Accused Products in "test/continuous mode" and in "normal mode." Doc. 56, Ex. 1 at 24-5. Lipson measures subjects' temperatures in these separate modes and concludes that because the results are different, there must be a calculation of deep tissue temperature and a correction for core body temperature. The Accused Products are not operated by first running in "test/continuous" mode, and then in "normal mode." Lipson never examines whether the Accused Products, in "normal mode" the only mode in which the products are sold ever first calculates deep tissue temperature and then corrects the calculated value for core temperature. Rather, Lipson intentionally mixes apples (a "test/continuous" mode) and oranges (a "normal" mode).

E. Lipson's 510(k) Proposed Testimony Requires No Expertise

BestMed's Motion relates to Lipson's opinions on what a 510(k) submission is, and K-Jump's purported intent related to its 510(k). Doc. 56 at 13-4. The function and purpose of a

510(k) requires no specialized knowledge. Id. Moreover, the credibility of witnesses and interpretation of witness testimony are for the factfinder, not an expert. *United States v. Lumpkin*, 192 F.3d 280, 290 (2d Cir. 1999). These opinions should be excluded.

F. Lipson's Enablement Opinions Ignore The Relevant Law And Are Based On An Incomplete Legal Framework

Lipson's faulty legal premise renders his enablement opinions legally irrelevant, and will only cause confusion. A specification must enable a person skilled in the art to practice the full scope of the claims without undue experimentation. *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed.Cir. 1997). The scope of the claims includes calculating a deep tissue temperature based on readings from a single temperature sensor. Yet, the patent does not teach how to achieve this. Medisim and Lipson seek refuge from the lack of enablement by relying on unrelated prior art. They argue that a specification need not disclose what is "well known in the art." Doc. 64 at 16-7. Resort to the prior art "is merely a rule of supplementation, not a substitute for a basic enabling disclosure." *Genentech*, 108 F.3d at 1365. Courts have made it clear that omission of "minor details" is allowed, but omitting a novel aspect of the claims is not. *Id*.

Calculating deep tissue temperature based on a skin surface temperature is not a "minor detail." Even Lipson does not so opine. Doc. 62 at 11. To the contrary, as stated as a Reason for Allowance, calculating deep tissue temperature is a purported novel aspect of the invention. Doc. 61, Ex. F. Lipson either ignores the law or was not made aware of it. Regardless, the undeniably flawed legal foundation renders Lipson's opinions unreliable.

G. Medisim's Survey Expert, Keegan, Should Be Excluded

Numerous flaws woven throughout Keegan's Report render his opinions unreliable. He fails to replicate market conditions, selects an improper universe, fails to utilize a proper control, and improperly biases his results. Doc. 56 at 17-24. Keegan even fails to define the character and scope of what he is testing. *See Gucci Am. Inc. v. Guess?, Inc.* 2011 WL 5825206 *6 (S.D.N.Y.

2011). These flaws, in the aggregate, warrant exclusion.

Keegan did not define his test market. Medisim tries to backfill by claiming Keegan is testing some marketplace three years prior. Doc. 64 at 19-20. Medisim's claim is at odds with Keegan's Report which discusses only the current market and products. Keegan cites an August 2011 website purportedly showing a BestMed thermometer at Rite Aid. Doc. 56, Ex. 10 at 8. Keegan further opines on the current state of Rite Aid's inventory that "[b]ecause Rite Aid does not currently offer for sale another Rite Aid branded digital temple thermometers . .. The control product was digitally modified..." Keegan never states that he is testing products and packaging from 2009. He also makes no reference to marketplace conditions existing at that time.

Regardless of the time frame, the Medisim-Manufactured and the K-Jump-Manufactured thermometers in his survey never co-existed. Doc. 56 at 18. Yet, he presented back-to-back pictures of these thermometers to respondents a situation that a consumer would have never faced. Any confusion measured in his fictitious world is meaningless given that consumers would have never encountered these specific products in the market. *See Thoip v. Walt Disney Company*, 690 F.Supp.2d 218, 236-7 (S.D.N.Y. 2010). Keegan's confusion rate predicated on fictitious market conditions, unattainable in reality, cannot be trusted.

Keegan's universe is also wrong. He polled thermometer users and not potential buyers. Doc. 56 at 21. Attempting to excuse this mistake, Keegan asserts that "one tries to define the population that most closely resembles the target market i.e., those consumers who would have exposure to the alleged infringement in the marketplace." Doc. 56, Ex. 10 at 5. Keegan wrongly equates patronizing a store with exposure to the alleged infringing activity. Visiting a store does not give one the ability to make "relevant distinctions" of all products offered. *See Weight Watchers Int'l., Inc. v. Stouffer Corp.*, 744 F.Supp. 1259, 1273 (S.D.N.Y. 1990). Rite Aid sells products ranging from apple juice to Zocor® . Keegan's claim that any shopper at Rite Aid can make "relevant distinctions" of each product offered is absurd. The universe must consist of

potential purchasers. Doc. 56 at 21. By limiting the population to users, Keegan selects a group who may have never seen the associated packaging in the marketplace. Accordingly, the opinion of an irrelevant population provides no information concerning the purported confusion.

Keegan's control is also flawed. Keegan's differences between his control and the experimental stimulus result in an under reporting of background "noise" and improperly inflate the confusion. *See Louis Vuitton* v. *Dooney & Bourke, Inc.*, 525 F.Supp.2d 558, 595 (S.D.N.Y. 2007). Medisim's laundry list of purported similarities between the control and the experimental stimulus confuses the matter. Doc. 64 at 22. "In designing a control group study, the expert should select a stimulus for the control group that shares as many characteristics with the experimental stimulus as possible, with the key exception of the characteristic whose influence is being assessed." Doc. 56, Ex. 11 at 258. Yet, Keegan fails to explain what protectable feature is being assessed. Moreover, the recited similarities, e.g. being "white" or having "clamshell packaging," fail to isolate the confusion attributable to any specific protectable interest and improperly attempts "protection for an unprotectable style, theme, or idea." *See Gucci*, 2011 WL 5825206 *6. Given Keegan's failure to offer a "precise expression of the character and scope" of the protectable interest being tested, it is impossible for his dissimilar control to isolate and account for the protectable interest whose influence is being assessed. *See Id.*

Medisim admits consumers have preexisting beliefs in that there is a misconception that "simply because two products are packaged with the same retail store's branding, they are made by the same manufacturer." Doc. 64 at 25. Keegan's attempts to account for these preexisting beliefs with the statement that "retail stores sometimes purchase such products from source manufacturers and sell them in the retail chain's store branded packaging." In so doing, Keegan improperly plants the idea that there is in fact a "relationship" between Rite Aid and the source manufacturers. It is impossible to determine which consumers were genuinely confused versus those biased by preexisting beliefs and Keegan's introductory statement.

Keegan improperly reinforces these preexisting beliefs by asking compound questions until he gets the answer he seeks. Keegan first asks whether the source manufacturers are the "same" or "different." When he gets an unfavorable result, Keegan rephrases the first question to get his desired result. Such compound questioning improperly influences the purported confusion rate, and have been rejected. *Georgia-Pacific v. Myers*, 2009 WL 2192721 *7 (W.D. Ark. 2009).

The Keegan Survey generates confusion rather than testing for it. Keegan's testing violates several major tenets of experimental research. Accordingly, his purported confusion rate cannot be trusted. Moreover, questions still remain as to what characteristics Keegan is testing and under what market conditions this testing occurred. The combined effect of Keegan's major flaws renders the Survey unreliable so as to provide no assistance to the trier of fact. The Keegan Report and Survey should be excluded in its entirety.

II. Conclusion

The Court's role is to act as a gatekeeper to opinion evidence that would be presented under the rubric of "expert" testimony. To that end, expert testimony must be vetted for reliability. Medisim's experts, however, wander far afield of acceptable practices both in methodology and in offering legal opinions, such as on the meaning of claim terms.

Medisim brought this baseless lawsuit. Yet, when forced to show its cards, Medisim and its experts fall woefully short of offering legitimate evidence, and rely instead on smoke and mirrors. Medisim's shenanigans must come to an end.[3] Accordingly, BestMed respectfully requests that, for the reasons presented, this Court grant its Motion to strike various portions of Medisim's expert's reports, and to exclude any testimony based thereon.

[3] Medisim's continuance of this case in the face of the Court's claim construction is itself a problem that may warrant sanctions. *See Martec, LLC. v. Johnson & Johnson*, Slip Op. 2010-1285, at pp. 21-22 (Fed.Cir. Jan. 3, 2012).

Respectfully submitted,

Dated: January 6, 2012

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on January 6, 2012, a copy of the foregoing **BESTMED, LLC'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO STRIKE PORTIONS OF PLAINTIFF'S EXPERTS, LIPSON AND KEEGAN** was electronically filed with the Court via ECF which thereby served an e-mail notice upon the attorneys listed below:

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